SEP 1 2 2003

510(k) Summary

K032552

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

Roche Diagnostics Corporation
9115 Hague Rd.
Indianapolis, IN 46250
(317) 845-2000
Contact Person: Scott Thiel
Date Prepared: August 18, 2003

2) Device name

Proprietary name: Accu-Chek Advantage System
Classification name: Glucose dehydrogenase, glucose test system
(21 C.F.R. § 862.1345)(75LFR)

3) Predicate device

We claim substantial equivalence to the current legally marketed Accu-Chek Advantage System.

4) Device Description

Instrument Operating Principle -- amperometric
Reagent Test Principle -- glucose dehydrogenase

5) Intended use

The Accu-Chek Advantage system is designed to quantitatively measure the concentration of glucose in capillary whole blood. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary, venous, arterial, and neonate (including cord) blood samples; lay use is limited to capillary whole blood testing.

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6) Similarities The Roche Diagnostics Accu-Chek Advantage (modified) System is substantially equivalent to the current legally marketed Accu-Chek Advantage (predicate) System. The proposed modification is relatively modest in scope. The following is a list of some of the claims and features unaffected by the proposed modification.

Feature/Claim	Detail
Intended use	The Accu-Chek Advantage system is designed to quantitatively measure the concentration of glucose in capillary whole blood. The device is indicated for professional use and over-the-counter sale. Professionals may use the test strips to test capillary, venous, arterial, and neonate (including cord) blood samples; lay use is limited to capillary whole blood testing.
Test principle	The enzyme glucose dehydrogenase converts the glucose in a blood sample to gluconolactone. This reaction liberates an electron that reacts with a coenzyme electron acceptor, the oxidized form of the mediator, hexacyanoferrate (III), forming the reduced form of the mediator, hexacyanoferrate (II). The test strip employs the electrochemical principle of biamperometry. The meter applies a voltage between two identical electrodes, which causes the reduced mediator formed during the incubation period to be reconverted to an oxidized mediator. This generates a small current that is read by the meter.
Monitor coding procedure	Code chip is provided with each carton of test strips.
Test strip storage conditions	Store at room temperature between +36° F (+2° C) and +86° F (+30° C).
Test strip operating conditions	Between +5° F (+10° C) and +104° F (+40° C).
Quality control testing frequency	Tests should be run with liquid quality control materials whenever a new vial of test strips is opened or an unusual blood test result is obtained.
Quality control acceptable range	The mean is strip lot specific and will be determined individually. The range of the controls is within ± 15 mg/dL or ± 15% compared to the determined mean.
Labeling instructions regarding expected results	The normal fasting adult blood glucose range for a non-diabetic is 70-105 mg/dL. One to two hours after meals, normal blood glucose levels should be less than 140 mg/dL. Doctors will determine the range that is appropriate for the patients.
Labeling instructions regarding response to unusual results	Run a quality control test, if the result is outside the acceptable QC recovery range contact Roche Diagnostics's Accu-Chek Customer Care center; if result is within the acceptable range, review proper testing procedure and repeat blood glucose test with a new test strip.

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510(k) Summary, Continued

6) Similarities (continued)

Feature/Claim	Detail
Acceptable sample types	Capillary whole blood samples from a fingerstick. Venous, neonatal, or arterial blood may also be used only if drawn by health care professionals.
Reportable range	10-600 mg/dL
Hematocrit range	20 - 65 % $<$ 200 mg/dl and 20 - 55% $\geq$ 200 mg/dl
Warnings and precautions	For *in vitro* diagnostic use only.

7) Data demonstrating substantial equivalence

Performance testing on the modified Accu-Chek Advantage (modified) System demonstrated that the device meets the performance requirements for its intended use. All predetermined acceptance criteria were satisfied. The data demonstrates that the Accu-Chek Advantage is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 12 2003

Mr. Scott Thiel
Regulatory Affairs Specialist
Roche Diagnostics Corporation
9115 Hague Road
P.O. Box 50457
Indianapolis, IN 46250-0457

Re: k032552
Trade/Device Name: Accu-Chek Advantage Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW
Dated: August 18, 2003
Received: August 19, 2003

Dear Mr. Thiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K032552

Device Name: Accu-Chek Advantage Test System

Indications for Use:

The Accu-Chek Advantage system is designed to quantitatively measure the concentration of glucose in capillary whole blood by persons with diabetes or by health care professionals in the home or in health care facilities. The device is indicated for professional use and over-the-counter sale.

Professionals may use the test strips to test capillary, venous, arterial, and neonate (including cord) blood samples; lay use is limited to capillary whole blood testing.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper, DVM

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032552

Prescription Use ____ OR Over-The-Counter Use ✓
(Per 21 CFR 801.109)

(Optional Format 1-2-96)